P21010.A07

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kanji TAKADA

Group Art Unit : 1615

Appl. No : 09/831,901
(National Stage of PCT/JP99/06602)

Examiner : Joynes

I. A. Filed : November 26, 1999

For : AN ORAL FORMULATION FOR GASTROINTESTINAL DRUG DELIVERY

ELECTION WITH TRAVERSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the requirement for restriction under 35 U.S.C. 121 and 372 mailed from the U.S. Patent and Trademark Office on May 20, 2003, which sets a one month shortened statutory period for response until June 20, 2003.

Applicant notes that this response is being filed prior to the expiration of the one month shortened statutory period for response, whereby an extension of time should not be necessary to maintain the pendency of the application. However, if any extensions of time are required to maintain the pendency of this application, this is an express request for any required extension of time, and authorization to charge any required fee to Deposit Account No. 19-0089.

Reconsideration and withdrawal of the requirement for restriction are respectfully requested in view of the remarks which follow:

RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

I. Claims 1-11, 22 and 23, drawn to an oral formulation in the form of a patch or tape.

II. Claims 12-21, drawn to an oral capsule formulation containing the patch or tape.

The Examiner asserts that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

The requirement asserts that the question of unity of invention has been reconsidered by the Examiner in view of the prior art cited in the first Office Action, and it is asserted that a review of U.S. Patent No. 4,765,983 makes clear that at least one feature is not novel over the prior art. IN particular it is asserted by the Examiner that:

> Furthermore, this reference appear to demonstrate that the patch or tape composition does not define a contribution which each of the inventions, considered as a whole, makes over the prior art; rather, it appears that the capsule formulation containing the patch or tape for delivery to the stomach or intestines imparts any potential novelty or unobviousness. Therefore, the instant claims have been restricted into a group that reflect the patch or tape that can be used in the oral cavity and a group that reflects the capsule formulation for delivery to the stomach or intestines.

Election

In order to be responsive to the requirement for restriction, Applicant elects Group II,, i.e., claims 12-21, with traverse.

However, for the reasons set forth below, Applicant submits that the restriction requirement is improper, and should be withdrawn, whereby an action on the merits of all of the pending claims is warranted.

Traverse

Notwithstanding the election of the claims of Group II in order to be responsive to the requirement for restriction, Applicant respectfully traverses the requirement.

The Examiner is reminded that in determining unity of invention, the criteria set forth in 37 C.F.R. 1.475 must be considered. Moreover, these criteria must be considered when making the requirement, and at least when performing a first action on the merits of the claimed invention. Thus, if any information regarding what the Examiner considers to be a "special technical feature" is present or should be present when a first Office Action on merits is prepared and mailed, such information should be taken into consideration at that time.

Still further, when making a restriction requirement, the requirement must establish that there is a "serious burden". In particular, as set forth in MPEP 803, "an appropriate explanation" must be advanced by the Examiner as to the existence of a "serious burden" if a restriction were not required.

In the instant situation, U.S. Patent No. U.S. Patent No. 4,765,983 was before the Examiner when the first Office Action on the merits was issued, and this patent was utilized as a primary reference in rejections of each of the pending claims. Moreover, the claims that were rejected based upon this patent were not substantively amended in the Amendment Under 37 C.F.R. 1.111, filed February 20, 2003, but should be considered to have been amended for cosmetic purposes.

Still further, the claims should be considered to be patentable over U.S. Patent No. 4,765,983, whether taken alone or combination with any prior art of record.

With the above in mind, Applicant respectfully submits that:

(a) A similarly claimed invention was before the Examiner when the first Office Action on the merits was mailed.

(b) U.S. Patent No. 4,765,983 was considered by the Examiner when the first Office Action was mailed.

(c) It is presumed that when a first Office Action on the merits is mailed that the examination is complete with respect to both compliance of the application with applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated. See 37 C.F.R. 1.104(a).

(d) The same prior art that was previously considered by the Examiner with respect to claims in both groups of invention is presently and therefore improperly being utilized to support a lack of unity of invention.

(e) The question of unity of invention should have already been considered by the Examiner when the first Office Action was mailed utilizing U.S. Patent No. 4,765,983 as the primary reference in the rejections set forth therein.

(f) A "serious burden" cannot be present when the claimed subject matter has already received an action of the merits, and this action of the merits included consideration of the same patent that is being utilized in an improper attempt to "reconsider" the question of unity of invention.

Still further, there should be no undue burden to examine all of the pending claims, because the International Searching Authority and International Preliminary Examination Authority have already performed a search of the subject matter recited in the two groups of invention.

In view of the lack of a "serious burden' in the present application, and the fact that a first Office Action on the merits has already issued in this application, Applicants respectfully submit that a lack of unity of invention can only be maintained with Group Director authorization and signature of the action.

In view of the foregoing, it is respectfully requested that the Examiner seriously reconsider the requirement for restriction, and withdraw the same so as to give an examination on the merits on all of the claims pending in this application.

CONCLUSION

For the reasons discussed above, it is respectfully submitted that the requirement for restriction is improper because unity of invention is present, and the requirement should be withdrawn.

Withdrawal of the requirement for the restriction with examination of all pending claims is respectfully requested.

Favorable consideration with early allowance of the application is most earnestly requested.

If the Examiner has any questions, or wishes to discuss this matter, the Examiner is requested to call the undersigned at the telephone number indicated below.

Respectfully submitted,
Kanji TAKADA

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June 20, 2003
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Attorney Docket No. P21010

In re application of : Kanji TAKADA

Mail Stop Non-fee

Serial No. : 09/831,901
(National Stage of PCT/JP99/06602)

Group Art Unit: 1615

Filed : May 25, 2001
(I.A. Filed: November 26, 1999)

Examiner: Joynes

For : AN ORAL FORMULATION FOR GASTROINTESTINAL DRUG DELIVERY

Mail Stop Non-Fee
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Transmitted herewith is an election with traverse in the above-captioned application.

___ Small Entity Status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a previously filed statement.
___ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
___ A Request for Extension of Time.
_X_ No additional fee is required.

The fee has been calculated as shown below:

Claims After Amendment	No. Claims Previously Paid For	Present Extra	Small Entity		Other Than A Small Entity	
			Rate	Fee	Rate	Fee
Total Claims:23	23*	0	x 9=	$0.00	x 18=	$
Indep. Claims: 1	*1*	0	x 42=	$0.00	x 84=	$
Multiple Dependent Claims Presented			+140=	$0.00	+280=	$
Extension Fees for Month				$0.00		$
			Total:	$0.00	Total:	$

*If less than 20, write 20
**If less than 3, write 3

___ Please charge my Deposit Account No. 19-0089 in the amount of $_____.
_N/A_ A Check in the amount of $_____ to cover the *filing/extension* fee is included.
_X_ The U.S. Patent and Trademark Office is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 19-0089.
_X_ Any additional filing fees required under 37 C.F.R. 1.16.
_X_ Any patent application processing fees under 37 C.F.R. 1.17, including any required extension of time fees in any concurrent or future reply requiring a petition for extension of time for its timely submission (37 CFR 1.136) (a)(3)

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